REMARKS

Claims 2, 4, 6, 9, 14-19, and 21-26 are pending in the present application. No new matter is inserted into the application.

Restriction Requirement

In response to the Restriction Requirement, Applicants elect Group I, claims 16, 2, 4, 6, 9, 17-19, and 21-24, drawn to a method for diagnosis or prognosis of a kidney disease, with traverse.

On page 3 of the Office Action, the Examiner alleges that the subject matter of Groups I through IV are not linked as to form a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features. However, on page 2 of the Office Action, the Examiner acknowledges that the claims of Group I are a "1st method of utilizing the special technical feature"; the claims of Group II are a "product comprising the special technical feature"; the claim of Group III is a "2nd method utilizing the special technical feature"; and the claim of Group IV is a "3rd method utilizing the special technical feature." Applicants respectfully submit that the Examiner misunderstands what is the "special technical feature" of the present invention and misapplies the PCT unity of invention

rules, such that the Restriction Requirement is improper and must be withdrawn.

Under PCT Rule 13 (which corresponds to 37 C.F.R. § 1.475) an application should relate to only one invention or, if there is more than one invention, an applicant has the right to include in a single application only those inventions which are so linked as to form a single general inventive concept. A group of inventions is considered linked to form a single general inventive concept when there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. See MPEP § 1893.03(d).

The special technical feature of the present invention is the assaying for liver-type fatty acid binding protein in a specimen collected from a patient. This special technical feature can be used to diagnose or prognose kidney disease (see claims of Group I), prognose the further progress of kidney disease (see claim 25, Group III), or determine the effect of medication on kidney disease (see claim 26, Group IV). Thus, the claims of Groups I, III, and IV are all method claims, and are therefore "claims in the same category."

The Examiner states, "Under PCT rules Applicant is entitled to an examination of one of the combination groupings: (1) a product

and a method of using it. Please see 37 CFR 1.475(b)." However, the Examiner fails to properly quote 37 C.F.R. § 1.475(b) and thusly mischaracterizes its meaning. Instead, 37 C.F.R. § 1.475(b) recites, "An international or national stage application **containing claims to different categories of invention** will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and process specially adapted for the manufacture of said product…[emphasis added]." As noted above, the claims of Groups I, III, and IV are all method claims, and are therefore "claims in the same category." Claims in the same category have unity of invention when the special technical feature is included in all claims.

For example, the Examiner's attention is drawn to Example 8 of the "Examples concerning unity of invention" (page AI-59 of the MPEP). In this example, claim 1 relates to a plug characterized by feature A and claim 2 relates to a socket characterized by corresponding feature A. The Example states that feature A is a special technical feature which is included in both claims 1 and 2 and therefore unity is present. Similarly, in the instant case, all the claims of Groups I, III, and IV recite the special technical feature of assaying for liver-type fatty acid binding protein in a specimen collected from a patient. Thus, the claims

are not of a "different category" and as such 37 C.F.R. § 1.475(b) does not apply.

Applicants acknowledge that the claims of Group II are of a different category that the claims of Groups I, III, and IV. Specifically, the claims of Groups I, III and IV are method claims while the claims of Group II are a **means specifically designed** for carrying out the claimed methods (again, each including the special technical feature of assaying for liver-type fatty acid binding protein in a specimen collected from a patient). The Examiner asserts that the product of Group II can be utilized in either of the "materially different" processes of Groups I, III, or IV, and therefore is not linked by the special technical feature to the claims of Groups I, III, and IV. Applicants respectfully disagree.

While it is true that the kit of Group II can be utilized in any of the methods of the claims of Groups I, III, and IV, this does not mean that the claims of Group II lack unity of invention with the claims of Groups I, III, and IV. Instead, 37 C.F.R. § 1.475(b) states that the combination of "a process and an apparatus or means specifically designed for carrying out said process" is considered to have unity of invention. Further, the Examiner's attention is drawn to the fact that the expression "specifically designed" does not imply that the means could not be used for

carrying out another process, nor that the process could not be carried out using an alternative means. See MPEP, Unity of Invention, Part 1, section e), page AI-54. Thus, the possibility that a kit can carry out another method, or that the method can be carried out without utilizing the kit is not conclusive. In the instant case, the kit of Group II is designed for carrying out the methods as noted by the Examiner. The special technical feature links all of these claims.

For all of the above reasons, Applicants respectfully request that the restriction requirement be withdrawn, and Groups I through IV be recombined. An early and favorable action on the merits of the present application is earnestly solicited.

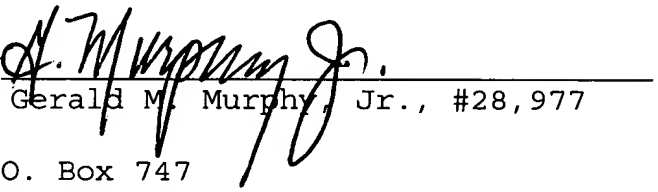
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. 45,702) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
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